

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON AT SEATTLE

LAUREN THOMPSON,

Plaintiff

v.

REGENCE BLUESHIELD; EXPEDIA
HEALTH & WELFARE BENEFIT
PLAN; EXPEDIA, INC., in its capacity
as Plan Administrator and/or Plan
Sponsor; and MCMC SERVICES, LLC,

Defendants.

No. 2:24-cv-1336

COMPLAINT FOR BREACH OF THE
EMPLOYEE RETIREMENT INCOME
SECURITY ACT OF 1974; FOR
DECLARATION OF RIGHTS; FOR
ENFORCEMENT AND CLARIFICATION OF
RIGHTS; AND FOR INJUNCTIVE RELIEF

COMES NOW THE PLAINTIFF, Lauren Thompson, and alleges as follows:

I. NATURE OF ACTION

This action arises under the Employee Retirement Income Security Act of 1974 (“ERISA”), 29 U.S.C. § 1001 *et seq.*

Plaintiff is a 39-year-old mother of two young children. She has stage IV metastatic melanoma. Her oncologist at the Fred Hutchinson Cancer Center certified that treatment with an FDA-approved medication, nivolumab-relatlimab-rmbw, is medically necessary to treat what he characterized as Plaintiff’s “refractory and life-threatening melanoma.”

1 Defendants denied Plaintiff the treatment and did so despite unequivocal testimony by
2 Plaintiff's oncologist that the treatment is "medically necessary" as the Plan defines that term.

3 Defendants' denial of the requested treatment violates the ERISA-governed employee
4 benefit plan under which Plaintiff's medical benefits are provided.

5 Plaintiff seeks a declaration of her rights under the Plan, and enforcement of those
6 rights, including immediate injunctive relief ordering Defendants to provide the medically
7 necessary treatment at issue.
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9 II. JURISDICTION AND VENUE

10 2.1 This Court's jurisdiction is invoked pursuant to 28 U.S.C. § 1331 and 29 U.S.C. §
11 1132(e)(1).

12 2.2 Venue is proper pursuant to 29 U.S.C. § 1132(e)(2) and 28 U.S.C. § 1391.
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14 III. PARTIES

15 3.1 Plaintiff is an adult, residing in Seattle, Washington.

16 3.2 Defendant Regence BlueShield is a Washington non-profit corporation.

17 3.3 Defendant Expedia Health and Welfare Plan is an ERISA-governed employee
18 welfare benefit plan.

19 3.4 Defendant Expedia, Inc., is the Plan Administrator and Plan Sponsor for the
20 Expedia Health and Welfare Plan and is sued here in those capacities.
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22 3.5 Defendant MCMC Services, LLC, is a Delaware limited liability company.

23 IV. FACTUAL ALLEGATIONS

24 4.1 Defendant Regence BlueShield ("Regence") is an independent licensee of the
25 nationwide BlueShield network of providers.
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1 4.2 Defendant Expedia Health and Welfare Plan (“the Plan”) is an employee welfare
2 benefit plan within the meaning of 29 U.S.C. § 1002(1).

3 4.3 Defendant Expedia, Inc., is the “Administrator” of the Plan as that term is defined
4 at 29 U.S.C. § 1002(16)(A).

5 4.4 Defendant Expedia, Inc., is the Plan “Sponsor” as that term is defined at 29 U.S.C.
6 § 1002(16)(B).

7 4.5 Defendant MCMC Services, LLC, is a Delaware limited liability company that
8 serves the insurance industry.

9 4.6 Regence is the claims administrator for the Plan.

10 4.7 Regence provides administrative services to the Plan, including deciding whether
11 medical services and supplies are provided to Plan participants and beneficiaries; deciding
12 whether to pre-authorize and allow coverage for some medical services and supplies; and
13 processing appeals under the Plan.

14 4.8 Expedia, Inc., pays for the medical services and supplies that Regence deems are
15 covered under the Plan.

16 4.9 Regence exercises authority or control respecting the management or disposition of
17 Plan assets and is therefore a “fiduciary” of the Plan as that term is defined by 29 U.S.C. §
18 1002(21); and/or is a “named fiduciary” of the Plan pursuant to 29 U.S.C. § 1133(2) and/or is a
19 “designated fiduciary” of the Plan pursuant to 29 U.S.C. § 1105(c)(1)(B).

20 4.10 Alternatively or additionally, Regence is a “functional” fiduciary.

21 4.11 Defendant MCMC Services, LLC exercises authority or control respecting the
22 management or disposition of Plan assets and is therefore a “fiduciary” of the Plan as that term is
23

1 defined by 29 U.S.C. § 1002(21); and/or is a “named fiduciary” of the Plan pursuant to 29 U.S.C.
2 § 1133(2) and/or is a “designated fiduciary” of the Plan pursuant to 29 U.S.C. § 1105(c)(1)(B).

3 4.12 Alternatively or additionally, MCMC Services, LLC is a “functional” fiduciary.

4 4.13 Plaintiff is a “participant” within the meaning of 29 U.S.C. § 1002(7) of the Plan.

5 4.14 Plaintiff is a “beneficiary” within the meaning of 29 U.S.C. § 1002(8) of the Plan.

6 4.15 As a beneficiary, Plaintiff is entitled to the health benefits set forth in the Plan.

7 4.16 The Plan provides coverage for medically necessary health services and supplies.

8 4.17 On or about July 8, 2024, Plaintiff’s oncologist asked Regence to pre-authorize
9 nivolumab-relatlimab-rmbw to treat what he described as Plaintiff’s “refractory and life-
10 threatening melanoma.”
11

12 4.18 On or about July 10, 2024, Regence denied the request for pre-authorization, and
13 refused to authorize coverage for nivolumab-relatlimab-rmbw to treat Plaintiff.
14

15 4.19 Regence stated that it denied the request because Plaintiff did not satisfy one of its
16 criteria for nivolumab-relatlimab-rmbw – that the patient had “no prior systemic therapy for
17 unresectable or metastatic disease.”

18 4.20 Plaintiff appealed this denial on or about July 10, 2024.

19 4.21 Regence denied Plaintiff’s appeal on or about July 19, 2024, citing the same
20 reason as it did when denying her oncologist’s request for pre-authorization.
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22 4.22 Plaintiff submitted a second appeal to Regence in accordance with the Plan’s
23 terms.

24 4.23 Regence denied Plaintiff’s second appeal on or about August 6, 2024, citing the
25 same reason as it did when denying her oncologist’s request for pre-authorization.
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1 4.24 In a sworn statement dated August 19, 2024, Plaintiff's oncologist explained that
 2 the criterion Regence relied upon to deny pre-authorization – that a patient has had “no prior
 3 systemic therapy for unresectable or metastatic disease” – was imported from the original
 4 clinical trials of nivolumab-relatlimab-rmbw and made no sense in the context of treatment.

5 His declaration states in relevant part:
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7 This particular criterion was rational in the context of clinical trials, in order to
 8 ensure a relatively homogenous cohort of patients. Clinical studies of medications
 9 often include such criterion; otherwise it would be difficult to determine the
 10 efficacy of the medication being tested. But there is no rational basis to apply that
 11 criterion in the context of standard treatment. When there are multiple FDA-
 12 approved treatment options available for a patient, one regimen will have to be
 13 chosen as the first-line option, and others will have to be used sequentially, as
 14 needed based on the response to prior regimen(s). In the case of Ms. Thompson,
 15 we chose ipilimumab plus nivolumab, also a standard treatment option regardless
 of the line of therapy, as the first treatment option for her metastatic disease.
 Denial of this FDA approved medication, especially given its proven
 effectiveness in metastatic melanoma, is a completely arbitrary and irrational
 decision by the insurer with potential grave implications for Ms. Thompson's life.

16 4.25 The Plan sets forth the following definition of “Medically Necessary” or “Medical
 17 Necessity”:

18 Medically Necessary or Medical Necessity means health care services or supplies
 19 that a Physician or other health care Provider, exercising prudent clinical
 20 judgment, would provide to a patient to prevent, evaluate, diagnose or treat an
 Illness, Injury, disease or its symptoms, and that are:

- 21 • in accordance with generally accepted standards of medical practice. “Generally
 22 accepted standards of medical practice” means standards that are based on
 23 credible Scientific Evidence published in Peer-Reviewed Medical Literature
 24 generally recognized by the relevant medical community, Physician Specialty
 25 Society recommendations and the views of Physicians and other health care
 Providers practicing in relevant clinical areas and any other relevant factors.
- 26 • clinically appropriate, in terms of type, frequency, extent, site and duration, and
 27 considered effective for the patient's Illness, Injury or disease;

- not primarily for the convenience of the patient, Physician or other health care Provider; and
- not more costly than an alternative service or sequence of services or supply at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's Illness, Injury or disease.

4.26 The following excerpts from Plaintiff's oncologist's August 19, 2024, declaration, demonstrate that nivolumab-relatlimab-rmbw is a "medically necessary" treatment for Plaintiff's illness, as that term is defined in the Plan. All italic and bold type emphasis is in the original declaration:

4.26(a) Ms. Thompson, a 39-year-old mother of two young children, has life-threatening, stage IV metastatic melanoma. She has rapidly progressing disease despite prior treatment with ipilimumab, nivolumab, binimetinib, and tumor infiltrating lymphocytes under a clinical trial. Her melanoma is unresectable, and without effective systemic therapy this young patient's life is at serious risk.

4.26(b) It is my professional judgment, and that of our multi-disciplinary oncology team at the Fred Hutch Cancer Center – a team that includes thought leaders in melanoma – that nivolumab-relatlimab-rmbw (Opdualag) is a highly appropriate FDA-approved therapy for Ms. Thompson's refractory and life-threatening melanoma. We have prescribed this treatment, but unfortunately the insurer has repeatedly denied pre-authorization.

4.26(c) It is our prudent clinical judgment that providing this medication to Ms. Thompson is squarely in accordance with generally accepted standards of medical practice. We have several patients in our clinic who received this combination for their refractory melanoma (not front-line setting) and experienced complete remission (i.e. no visible tumors left behind), which has been life saving for these patients. In addition to our own clinical experiences, there are several credible scientific studies published in medical journals that meet nationally recognized requirements for scientific manuscripts, and which submit most of their published articles for review by

experts who are not part of the editorial staff, that show strong data regarding the efficacy of nivolumab-relatlimab-rmbw in both front-line *and in refractory melanoma patients*. See Ascierto PA, et al., Nivolumab and Relatlimab in Patients With Advanced Melanoma That Had Progressed on Anti-Programmed Death-1/Programmed Death Ligand 1 Therapy: Results From the Phase I/IIa RELATIVITY-020 Trial. J Clin Oncol. 2023 May 20;41(15):2724-2735. doi: 10.1200/JCO.22.02072. Epub 2023 Feb 13. PMID: 36780608; PMCID: PMC10431305, reporting on a clinical study that concluded, “Nivolumab and relatlimab had a manageable safety profile and ***demonstrated durable clinical activity in a proportion of patients with heavily pretreated advanced melanoma*** with prior progression on anti-PD-(L)1-containing regimens.” See also Xu J, Mu S, Wang Y, Yu S, Wang Z. Recent advances in immunotherapy and its combination therapies for advanced melanoma: a review. Front Oncol. 2024 Jul 16;14:1400193. doi: 10.3389/fonc.2024.1400193. PMID: 39081713; PMCID: PMC11286497, stating that for “advanced melanoma patients who have progressed *after receiving previous treatment* (including anti-PD-1 therapy), relatlimab combined with nivolumab can also bring long-lasting survival benefits.” See also Sorino C, Iezzi S, Ciuffreda L, Falcone I. Immunotherapy in melanoma: advances, pitfalls, and future perspectives. Front Mol Biosci. 2024 Jun 28;11:1403021. doi: 10.3389/fmolb.2024.1403021. PMID: 39086722; PMCID: PMC11289331 noting that “the combination of relatlimab and nivolumab had satisfactory and durable clinical results in patients with metastatic melanoma *that were previously treated with PDL-1 inhibitors*.” [internal exhibit references omitted].

4.26(d) Our determination that nivolumab-relatlimab-rmbw is medically necessary to treat Ms. Thompson’s metastatic melanoma is not only in accordance with generally accepted standards of medical practice, and based on credible scientific studies published in nationally recognized medical journals, but also supported by the United States Food and Drug Administration (“the FDA”), which has approved nivolumab-relatlimab-rmbw for treatment of stage IV melanoma, *regardless of the line of therapy*.

1 4.26(e) Further, use of nivolumab-relatlimab-rmbw for metastatic melanoma
2 is supported by national guidelines, including the National
3 Comprehensive Cancer Network. See page 54 of the NCCN
4 Guidelines Version 2.2024, for Melanoma: Cutaneous, identifying
5 the medication as a “*preferred regimen*” for “*second-line or*
6 *subsequent therapy*” for metastatic or unresectable melanoma[.]

7 4.26(f) Treatment with nivolumab-relatlimab-rmbw is unquestionably
8 clinically appropriate given the type, extent, site and duration of
9 Ms. Thompson’s disease and considered effective for her disease

10 4.26(g) We [the oncology team at Fred Hutchison] have not recommended
11 nivolumab-relatlimab-rmbw for our convenience, or the
12 convenience of the patient or any other health care provider.

13 4.26(h) There is *no FDA-approved alternative service or sequence of*
14 *services that is as likely to produce equivalent therapeutic results*
15 *or to be as effective in the treatment of Ms. Thompson’s*
16 *refractory melanoma.*

17 4.27 Following Regence’s denial of her second appeal Plaintiff requested review by
18 an “Independent Review Organization” (“IRO”) in accordance with the Plan’s terms.

19 4.28 Regence and/or the Plan and/or Plan Administrator used MCMC Services, LLC to
20 act as the purportedly independent reviewer.

21 4.29 Regence provided the oncologist’s August 19, 2024, declaration and other
22 information to MCMC Services, LLC.

23 4.30 On or about August 23, 2024, MCMC Services, LLC, stated it had decided the
24 denial of coverage for nivolumab-relatlimab-rmbw “should be upheld.”

25 4.31 MCMC Services, LLC explained its decision by citing the same explanation
26 Regence provided when denying pre-authorization and coverage, and when denying Plaintiff’s
27 two appeals – that the treatment was “not medically necessary because this patient has been
previously treated for metastatic melanoma.”

1 4.32 MCMC Services, LLC, stated that nivolumab-relatlimab-rmbw “does not meet
2 the plan definition of a medically necessary treatment” for Plaintiff.

3 4.33 This is incorrect. For all the reasons stated by Plaintiff’s oncologist, nivolumab-
4 relatlimab-rmbw is “medically necessary,” as that term is defined in the Plan, to treat
5 Plaintiff’s life-threatening illness.
6

7 4.34 Defendants wrongfully denied Plaintiff’s claim for benefits under the Plan, and
8 wrongfully refused to pre-authorize and authorize coverage of nivolumab-relatlimab-rmbw.

9 4.35 Defendants refused to pre-authorize and provide nivolumab-relatlimab-rmbw
10 for Plaintiff despite knowing that the treatment is “medically necessary” under the Plan’s
11 terms.
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13 4.36 Defendants failed to properly and adequately investigate the merits of Plaintiff’s
14 request and/or consider the information provided by Plaintiff.

15 4.37 Defendants failed to consider the overwhelming medical evidence
16 demonstrating that nivolumab-relatlimab-rmbw is medically necessary to treat Plaintiff’s
17 melanoma.

18 4.38 Defendants’ use of a criterion designed to ensure a homogenous cohort of
19 patients in a clinical study as a criterion in the context of standard treatment is arbitrary and
20 irrational and violates the terms of the Plan.
21

22 4.39 Defendants failed to provide coverage for Plaintiff’s treatment in violation of
23 the express terms of the Plan, which promises to pay benefits to Plan participants and Plan
24 beneficiaries for medically necessary treatment.

25 4.40 Plaintiff has exhausted all of her so-called “administrative remedies” before
26 filing this action.
27

V. STATEMENT OF CLAIMS

5.1 Plaintiff re-alleges and incorporates by reference Paragraphs 4.1 through and including 4.40 above.

5.2 ERISA imposes higher-than-marketplace quality standards on plan fiduciaries and requires them to discharge their duties in respect to claims processing “solely in the interests of the participants and beneficiaries” of the Plan. 29 U.S.C. § 1104(a)(1).

5.3 ERISA also underscores the particular importance of accurate claims processing and evaluation by requiring that administrators provide a “full and fair review” of claim denials. 29 U.S.C. § 1133(2).

5.4 Defendants breached their fiduciary duties to Plaintiff when they failed to comply with their obligations under 29 U.S.C. § 1104 and 29 U.S.C. § 1133 to act solely in the Plaintiff’s interest and for the exclusive purpose of providing benefits to ERISA participants and beneficiaries, and to provide a full and fair review of Plaintiff’s claims.

5.5 Defendants’ failure to pre-authorize and provide coverage for Plaintiff’s medically necessary treatment with nivolumab-relatlimab-rmbw violated the terms of the Plan and violated generally accepted standards of care.

5.6 Defendants’ failure to pre-authorize and provide coverage for Plaintiff’s medically necessary treatment with nivolumab-relatlimab-rmbw denied Plaintiff her rights under the Plan.

5.7 Pursuant to 29 U.S.C. § 1132(a)(1)(B), Plaintiff seeks to enforce her rights under the Plan and seeks a Declaration from this Court, as described below, that nivolumab-relatlimab-rmbw is “medically necessary” under the Plan, and an Order directing Defendants to immediately authorize and provide that treatment in accordance with the Plan’s terms.

Plaintiff prays for entry of judgment as follows:

6.2 That this Court declare that by denying Plaintiff this medically necessary treatment, Defendants violated the terms of the Plan and denied Plaintiff her rights under the Plan;

6.3 That this Court declare that Defendants breached their fiduciary duties to Plaintiff;

6.4 That this Court enjoin Defendants from continuing to deny Plaintiff the medically necessary treatment she has requested and which the Plan requires them to provide, and do so by issuing a temporary restraining order directing Defendants to immediately authorize and provide coverage for nivolumab-relatlimab-rmbw;

6.5 That this Court enjoin Defendants from continuing to deny Plaintiff the medically necessary treatment she has requested and which the Plan requires them to provide, and do so by issuing a preliminary injunction directing Defendants to immediately authorize and provide coverage for nivolumab-relatlimab-rmbw;

6.6 That this Court enjoin Defendants from continuing to deny Plaintiff the medically necessary treatment she has requested and which the Plan requires them to provide, and do so by issuing an Order directing Defendants to immediately authorize and provide coverage for nivolumab-relatlimab-rmbw;

1 6.7 That this Court order Defendant to pay Plaintiff her attorney's fees and costs
2 pursuant to 29 U.S.C. § 1132(g)(1); and

3 6.8 That Plaintiff be awarded any additional and further relief which this Court finds
4 just and equitable, or which the Court deems necessary and proper to protect Plaintiff's
5 interests.
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7 DATED this 26th day of August 2024.

8 LAW OFFICE OF MEL CRAWFORD
9

10 By s/Mel Crawford
11 Mel Crawford, WSBA #22930
12 Attorney for Plaintiff
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